

# CHOOSING THE RIGHT PLM FOR THE MEDICAL DEVICE DIGITAL THREAD

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# Choosing the Right PLM

## Supporting the Digital Thread Initiative

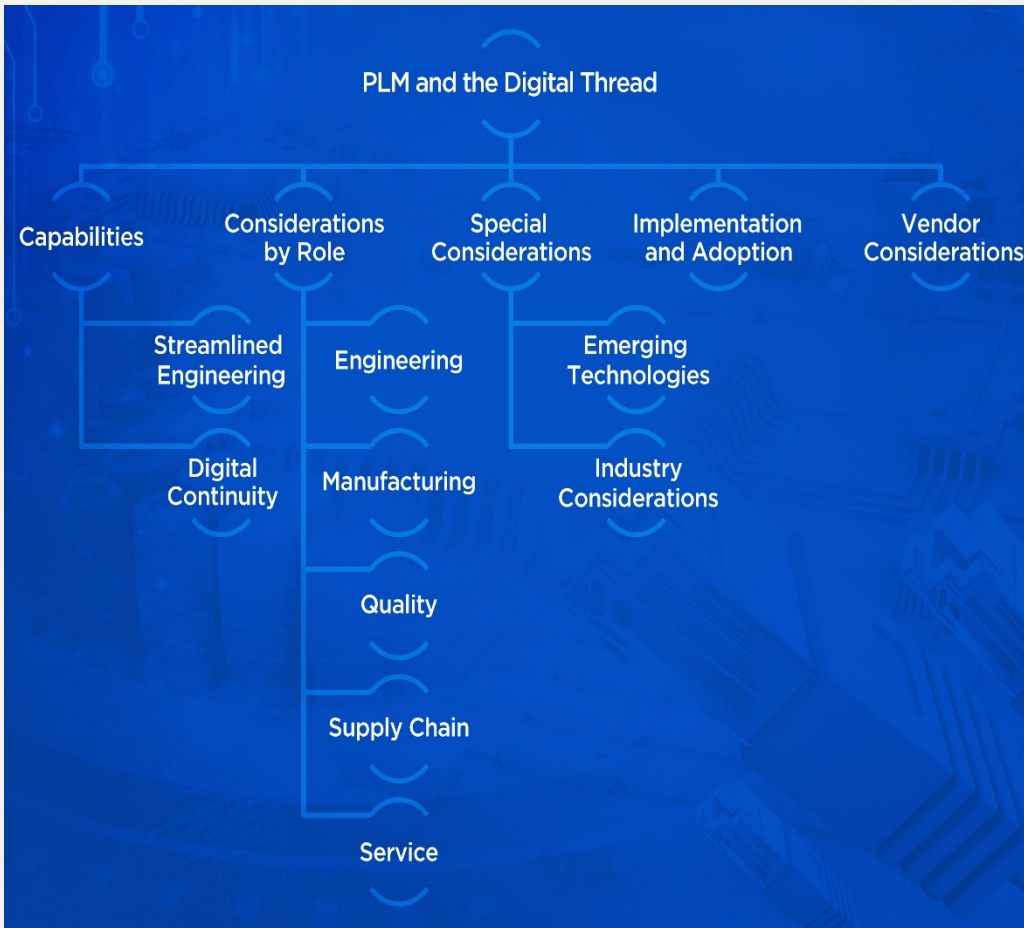
Over three-quarters of medical device manufacturers view the digital thread as either important or critical to achieving their business strategy. How can PLM enable them to streamline engineering and create digital continuity with a cohesive digital thread that allows them to improve closed-loop quality and patient outcomes while meeting complex, regional compliance demands?



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# Introducing the Buyer's Guide



## Digital Thread and PLM Survey Highlights

A recent survey of over 250 manufacturers and engineering firms with additional focus on 26 that serve the Medical Device / Life Sciences Industry highlights the strategic value of the digital thread and the vital role that PLM plays in achieving their objectives.

What should these companies look for when they select an enterprise PLM solution to support their digital thread?

## Structure of this Guide

This buyer's guide analyzes the strategic value of the digital thread and then shares the things companies should consider when choosing a supporting solution. The guide shares functional requirements needed to streamline engineering and create digital continuity across the product lifecycle. It also shares some critical things to look for by key roles in the manufacturing enterprise.

The guide then goes beyond functional considerations to identify special considerations, vendor requirements, and important factors to ensure successful implementation and adoption. For broader requirements for the Medical Device industry please see our Medical Device Manufacturers Software Selection Guide for 2019.

# The Digital Thread Imperative

## Business Strategies Demand a Cohesive Digital Thread

Over three-quarters of companies say that the digital thread is either important or critical to achieving their business strategy. About one-half of medical device manufacturers indicate they have implemented a digital thread initiative, most likely to meet design control mandates such as Design History File (DHF) and Device Master Record (DMR) and rapidly changing, region-specific regulatory requirements such as EU Medical Device Regulation (MDR).

Medical device manufacturers report a variety of important goals for their digital thread initiative (see chart). They are 30% more likely than other manufacturers to pursue compliance, for

example seeking audit-ready data. They are investing in reducing errors and adverse events to improve patient outcomes, all while trying to control the cost of quality and compliance overhead.

While definitions vary, medical device manufacturers are looking for quality, compliance, and streamlined engineering.

## Streamlined Engineering

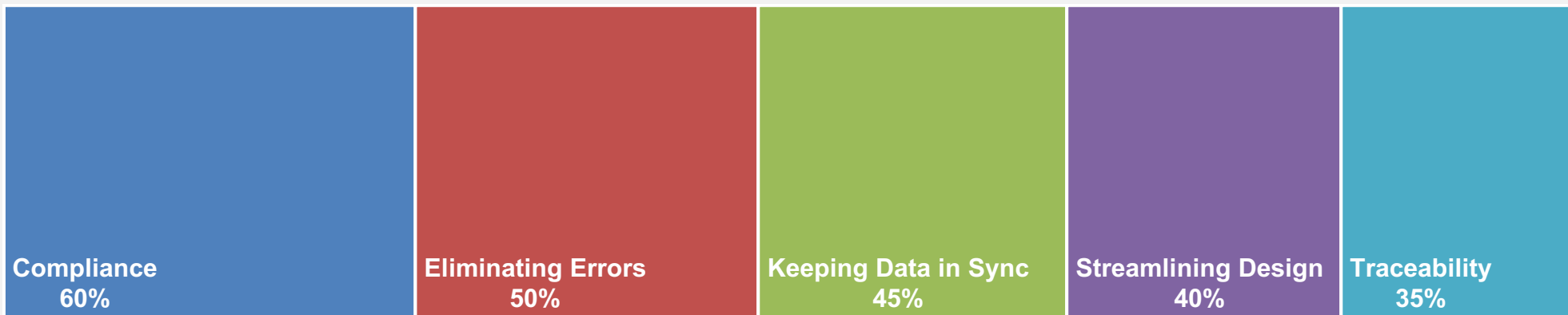
The digital thread streamlines design by allowing product development teams to share and reuse design data across the stages of innovation. Design continuity along the digital thread allows engineers to add their design information to a cohesive model, directly incorporating and extending design data from prior

steps – allowing them to efficiently design for regulatory management.

## Continuity, Closed Loop Quality

The digital thread ties product information, decisions, and history together in a structured, integrated way that captures product innovation and knowledge throughout the product lifecycle. It establishes traceability from early in the front end of innovation through development, manufacturing, service, and field operation. This continuity ensures data-driven handovers between departments and support for evolving global regulations, initiatives, and standards including the FDA’s Case for Quality (CfQ) and Quality System Regulation (QSR), ISO 13485, and the new EU MDR/EU IVDR.

MEDICAL DEVICE INDUSTRY DIGITAL THREAD INITIATIVE GOALS



# What to Look for to Streamline Engineering

## The Digital Thread Allows Efficient Design for Regulatory Management

Companies turn to the digital thread to address common engineering challenges such as improving design efficiency, reusing design data, and improving data access. The digital thread provides a single source of product data that can be easily retrieved and reused. These improvements lead to higher engineering efficiency and faster design cycles that can allow for faster product launches or more time to innovate, iterate, and optimize designs.

## Requirements

Companies need the right capabilities to streamline engineering with the digital thread. The table on this page shares some important buying considerations for them to consider when they choose enterprise software, including PLM, to support their digital thread. It's not an all-encompassing list but instead focuses on some key features that are important for successful streamlining. The capabilities provide value to engineers in more ways than creating the digital thread.

The need to streamline and improve engineering in the era of COVID-19 must now support remote work. This is essential because policies and procedures were not developed with an expectation that employees would work from home.

Companies that have adopted a digital thread enable their technical resources to spend 10% more value-added time on innovation, design, and development work.

## DIGITAL THREAD: REQUIREMENTS TO STREAMLINE ENGINEERING

Ability to quickly find and access product data

Digitally accessible data  
(versus scanned or proprietary formats)

Data can be reused across lifecycle steps  
(without reentry or translation)

Holistic digital product design model

Auditable tracking of design history / decisions

Region-specific, structured documents and  
package submission

Dashboards and reporting

Change and release management

# What to Look for in Closed-Loop Quality, Continuity

## DIGITAL THREAD: REQUIREMENTS FOR CLOSED-LOOP QUALITY, CONTINUITY

Data integrated across engineering, manufacturing, operations, service

CAD tool neutrality with ability to use CAD files in their original master format

Data kept in sync across steps with digital product traceability

Documented designs and design decisions

Integrated product history across the steps in the lifecycle

Reliability prediction and analysis based on history

Support for design control standards including DHF, DMR, EU MDR

## The Digital Thread Provides Continuity and Traceability

The digital thread provides value by providing a complete, integrated body of product knowledge. This data goes beyond the enterprise capturing quality field data from deployed equipment and adverse events. Medical device manufacturers are 56% more likely to extend their digital thread to include regulators. This information provides end-to-end product traceability and supports better product testing, validation, and service response time. A centralized, integrated digital thread also eases the burden of manually assembling data for compliance reporting in multiple formats and languages.

## Requirements

PLM provides the digital product data backbone that creates the digital thread. The table on this page highlights key considerations to support digital continuity. Again, it's not an all-encompassing list, and we acknowledge that the requirements in this section overlap with objectives discussed elsewhere in the eBook.

42% of medical device manufacturers indicate that keeping data in sync across the product lifecycle is a challenge, creating challenges for requirements like the FDA's Total Product Life Cycle (TPLC).

# Digital Thread Business Value

## Benefits of the Digital Thread

The digital thread drives quality and continuity improvements that can reduce the cost of poor quality (CoPQ), drive higher overall equipment effectiveness (OEE), and decrease service cost. Streamlining engineering improves efficiency and speeds up compliance cycle times and time-to-market. Creating digital continuity helps improve speed, efficiency, and innovation in addition to testing, validation, quality, traceability, and compliance. Survey responses confirm the strategic business value of the digital thread.

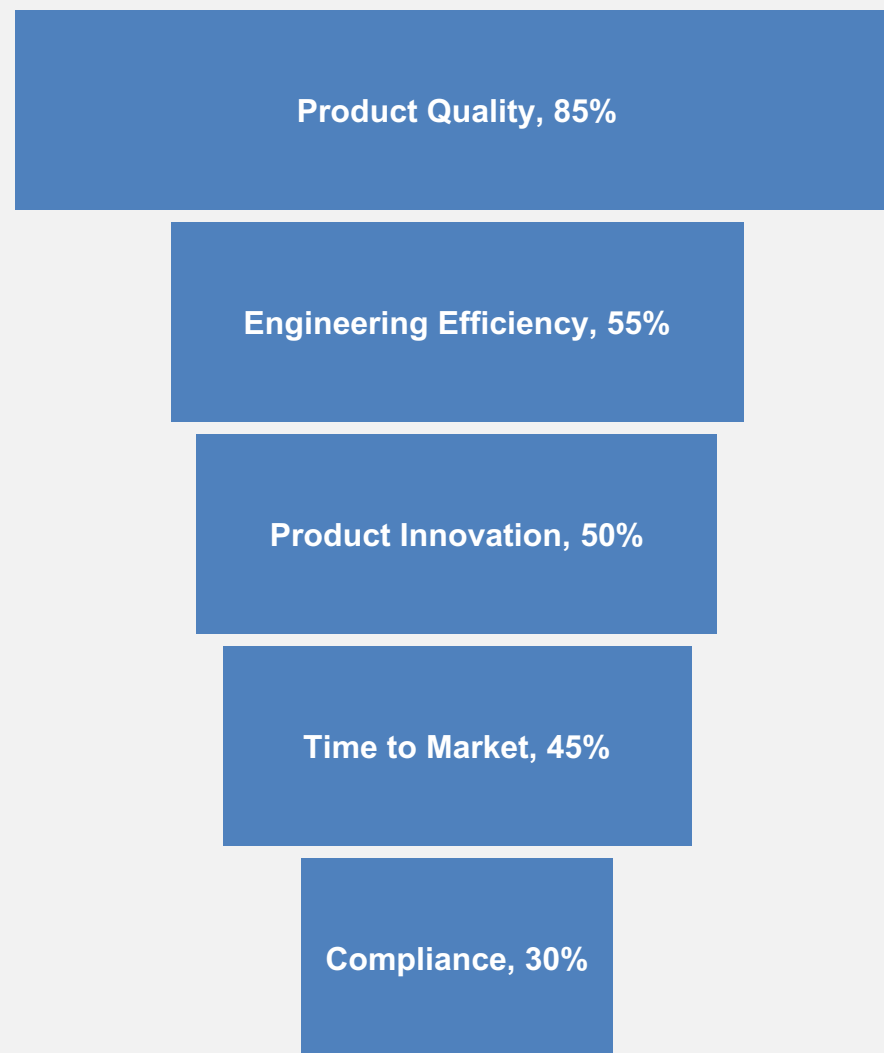
## Measurable Business Results

Digital thread improvements result in tangible advantages. Top Performers, those that outperform their competitors across key product development metrics, are almost two and one-half times as likely to have already implemented a digital thread initiative\*.

More directly, survey analysis shows that technical resources from companies that have implemented a digital thread initiative spend 10% more time on value-added innovation, design, and development work. These are strategic, competitive advantages. This is essential for medical device manufacturers who have traditionally traded off essential innovation and design time to focus on compliance documentation that could be automated.

\* For more information on the Performance Banding Methodology used to identify Top Performers, please see the *About the Research* section.

## MEDICAL DEVICE INDUSTRY DIGITAL THREAD BUSINESS BENEFITS





# Considerations by Role – Engineering

## DIGITAL THREAD: REQUIREMENTS FOR ENGINEERING

Tight integration of CAD in the digital product model

Multi-CAD support

Incorporation and integration of MCAD, ECAD, and software design

Integration of product and process operational data from the IoT

Inclusion of modeling and simulation data

Systems engineering perspective

Remote engineering collaboration

## Reduce Non-Value-Added Time

Survey results show that technical resources like engineers spend only 49% of their time, on average, on value-added innovation, design, and development work. They spend non-value-added time on data management, searching for information, recreating data, collecting data for others (such as for status updates, meetings, and supporting changes), incorporating changes made by others, administration, and more. These challenges are commonplace, with 45% of respondents indicating that the impact of traceability, data continuity, and data management challenges is engineering inefficiency.

PLM and the digital thread help drastically reduce the need for non-value-added activities. The increased efficiency allows them more time to experiment, innovate, and optimize designs. Feedback from the field can also help engineers continuously improve designs, improve quality, lower risk, and reduce adverse events. Please see the table on this page for some additional considerations for Engineering.

Two-thirds of Engineering participants that have implemented a digital thread initiative report improved engineering efficiency.

# Considerations by Role – Manufacturing

## Improve Data Accessibility and Synchronization

Manufacturing relies on correct, up-to-date product data from Engineering to produce high-quality products and get them to market quickly. Over one-half of Manufacturing participants (57%) share that simply making product information readily accessible is a goal of their digital thread initiative, improving production preparation and access to data on the shop floor. Further, over one-half of Manufacturing participants share that keeping product data synchronized across the lifecycle is a goal of their digital thread initiative. Manufacturing is about 50% more likely than other departments to state these goals, with data synchronization at the top of their list.

Medical device manufacturers are becoming more supply-chain-centric in design and manufacturing, leveraging contract design and manufacturing resources. The digital thread must readily extend to the supply chain in addition to company facilities.

COVID-19 has placed additional strains on plants as they are forced into production for devices and protective equipment that they have never produced before. The digital thread helps by making data accessible and synchronized across the business and the supply chain. Please see the table on this page for some additional considerations for Manufacturing.

Medical device manufacturers are 30% more likely to have suppliers / supply chain participate in their digital thread.

## DIGITAL THREAD: REQUIREMENTS FOR Manufacturing

Product design model that includes production steps

Integrated tooling and equipment in the production model

Visual work instructions including training, tracking, and certification to ensure the right person performed a particular task

Manufacturing data incorporated in the digital thread with production execution traceability

Integrated data from the IoT to capture production actuals and feed that data back to Engineering and Manufacturing

Strategic sourcing needs including AML / AVL, sharing specifications, and quality requirements for shipping and incoming items

Support for nonconformance, CAPA, and SCAR (Supplier Corrective Action Report) processes

# Considerations by Role – Quality

## DIGITAL THREAD: REQUIREMENTS FOR QUALITY

Data associated with requirements for validation and traceability

SOP training and tracking

Ability to digitally capture and associate test results

Comprehensive, centralized data with analytics for root cause analysis

Closed loop quality with integrated FMEA tied to manufacturing and field data

Integrated QMS capabilities meeting ISO 13485 requirements

Provide the ability to extend the digital thread to regulators

## Integrate Data for Validation and Traceability

Today's complex products and the need to protect patient safety demand a cohesive approach to testing and validation, starting at the requirements level and spanning disciplines. The top traceability challenge related to the digital thread is testing and validation, as reported by about one-half of Medical Device Industry respondents. Over one-third of companies state that traceability, data continuity, and data management challenges lead to quality problems, the second most commonly cited business impact in the survey. The same number of respondents report repeating mistakes despite lessons learned from past problems, preventing companies from continuously improving.

The digital thread with PLM provides the integrated data framework for this information, whether the data is all encompassed within PLM or referenced in other systems. This integration allows companies to improve quality, reduce risk, and prevent late mistakes that impact the cost of poor quality and time to market. Please see the table on this page for some additional considerations for Quality.

85% of Medical Device Industry participants report that the digital thread has improved product quality.

# Considerations by Role – IT

## Improve Overall Product Development Efficiency

Information Technology is often responsible for improving processes and efficiency across the company, so the benefits to IT are more company-wide than IT-specific. IT sees the lack of continuity and integration more keenly than others, with two-thirds of IT participants reporting a lack of data integration across the lifecycle and 60% reporting the need to recreate design data between steps as issues. They see the resulting inefficiency across different departments and steps in the lifecycle, including lost time and errors.

## Make Data Available for Compliance Reporting

Although Quality plays an important role, IT is frequently involved in compliance reporting. About one-half of IT participants report the complexity of compliance reporting is a challenge. Compliance reporting frequently requires manual intervention to organize data in the right format for different people and purposes, even when data is captured electronically. Fortunately, over one-half of IT participants report easier or better compliance as a benefit of the digital thread. Adopting Medical Device Single Audit Program (MDSAP) increases requirements, but may simplify reporting.

The digital thread helps reduce friction in the product development process to improve efficiency. It also brings cross-functional data together to make compliance reporting less cumbersome. Please see the table on this page for some additional considerations for IT.

70% of IT participants report faster time to market from the digital thread.

### DIGITAL THREAD: REQUIREMENTS FOR IT

Extendable data model

Easy to integrate with external data

Automated tasks, workflows, design automation

No need for design translations or data viewers

Ability to provide visual design data to downstream departments, including AR

Reporting tools that ease compliance reporting and translation from history data

Proven design and document control capabilities

Support for HIPPA, ISO 21CFR, TLPC, UDI, and MDSAP

# Considerations by Role – Service

## DIGITAL THREAD: REQUIREMENTS FOR SERVICE

Ability to transform product data to support service

Capability to augment product data with service data with event reporting / trending

Streamlined development and management of controlled service documentation

Visual user interface (Augmented Reality) for service instructions by configuration

Product performance monitoring with the IoT for faster response to adverse events, customer self-service, and higher uptime

Predictive analytics to grow service business and support a transition to new business models

Provide data for supply chain optimization

## Include Service Closely in the Digital Thread

Service in the medical device industry plays a critical role in driving safety, patient outcomes, and compliance. The lack of an effective digital thread means a lack of data continuity, leading to recreating design data between steps, difficult change impact analysis, and challenges keeping data in sync across the lifecycle. 46% of service respondents report that eliminating errors is a key goal of their digital thread initiative. Unfortunately, only about one-third of surveyed companies include service information in the scope of their digital thread, less than engineering, quality, and manufacturing information. Medical device companies are, however, 32% more likely to include service plans / instructions in the scope of their digital thread.

## Transform Service with IoT and Analytics

Service is transforming to become more predictive. One way companies do this is by monitoring equipment to predict and prevent performance issues. Gathering operational data from the IoMT (Internet of Medical Things) provides a rich source of information, particularly when integrated with additional data. Analytics can create insights from the data to improve service performance. For more, see *Buyer's Guide: Improving Service with Remote Monitoring*. Please also see the table on this page for additional Service considerations.

Top Performers are 44% more likely to use analytics on top of their digital thread to gain insights.

# PLM is the Digital Thread Backbone

## The Digital Thread Relies on PLM

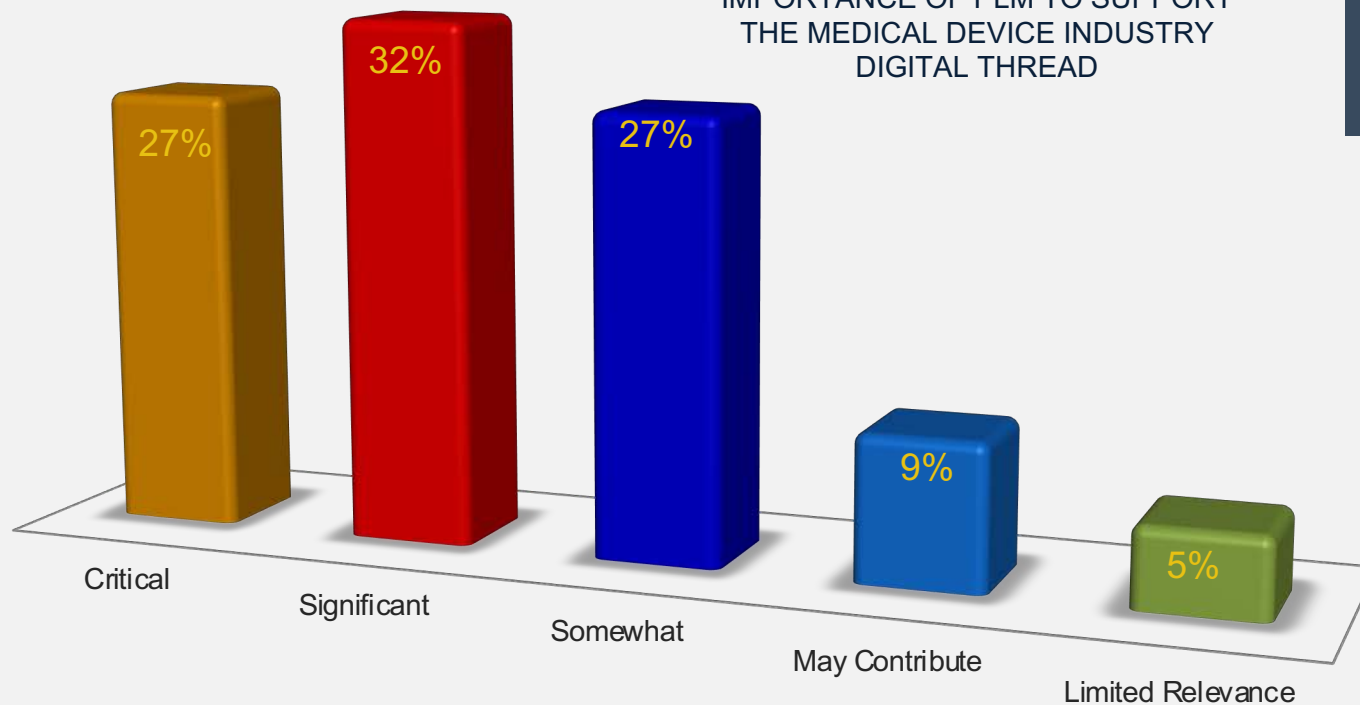
Survey analysis shows how crucial PLM is to support the digital thread. Over one-half of medical device manufacturers responding to the survey say that PLM is either important or critical to supporting a digital thread initiative. PLM provides the data model and processes that lead to digital continuity and improved engineering efficiency, making it the digital backbone of the manufacturing enterprise.

## PLM Delivers Better Results

The survey finds that not only are companies turning to PLM but that they are getting better business results because of it. For example, companies that use PLM to support the digital thread are 51% more likely to report improved engineering efficiency from their digital thread efforts than those that are not using PLM for their initiative.

Companies that use PLM to support the digital thread are 51% more likely to improve engineering efficiency from their digital thread efforts.

IMPORTANCE OF PLM TO SUPPORT THE MEDICAL DEVICE INDUSTRY DIGITAL THREAD



# Special Considerations – Emerging Technologies

## PLM is Expanding

PLM solutions are expanding to become more comprehensive Product Innovation Platforms. PLM has already been expanding in five primary areas:

- Incorporating a broader scope of the product definition
- Extending to more product development roles
- Supporting a wider variety of business processes
- Covering further up and downstream in the product lifecycle
- Integrating more fully into the manufacturing systems ecosystem

Beyond this incremental expansion, PLM platforms are incorporating more advanced technologies and supporting more advanced digital initiatives. It's crucial to recognize how these enable and extend the digital thread.

## IoT

The digital thread shouldn't stop when the product is shipped. Monitoring products via the IoMT allows engineers to understand how designs perform in the plant and the field. This feedback allows continuous improvement and collaboration between Engineering, Manufacturing, and Service.

## Analytics

Coupled tightly with IoT, advanced analytics can help make sense of IoT information. This extends the digital thread to further enhance continuous improvement, in addition to improving service and performance. For more, see our buyer's guide, *Improve Service by Monitoring Customer Equipment*.

## The Digital Twin

There is a lot of synergy between the capabilities required for the digital thread and those needed for the digital twin. A comprehensive digital thread in PLM provides the details needed to support a rich, complete digital twin. The digital twin allows companies to simulate and optimize product performance and take maintenance operations to the next level.

## Augmented Reality

AR can help companies improve design and planning tasks and enable the use of PLM data through Manufacturing and Service. For example, plant or service personnel can leverage up-to-date work or service instructions based on digital thread configuration data from anywhere in the world. In addition, AR has proven success in delivering medical device training and may help demonstrate device capabilities to improve sales and marketing.

Top Performers are 2.8 times more likely to use IoT data to extend the digital thread with production and/or field data from the physical product.

# Implementation Considerations

## Implementation and Adoption

Selecting the right software without ensuring implementation, adoption, and support would be short-sighted. Companies should consider essential aspects related to implementing and adopting the solution. These factors include systems validation and the ability to implement core capabilities quickly, gain value, and expand over time.

User training is a vital adoption consideration. The digital thread is a new concept and drives widespread use of the PLM system across the company. Effectively onboarding these individuals to new business concepts and software is vital. Most digital thread initiatives also benefit from business transformation advisory services to ensure process alignment and reach the full potential value of the initiative.

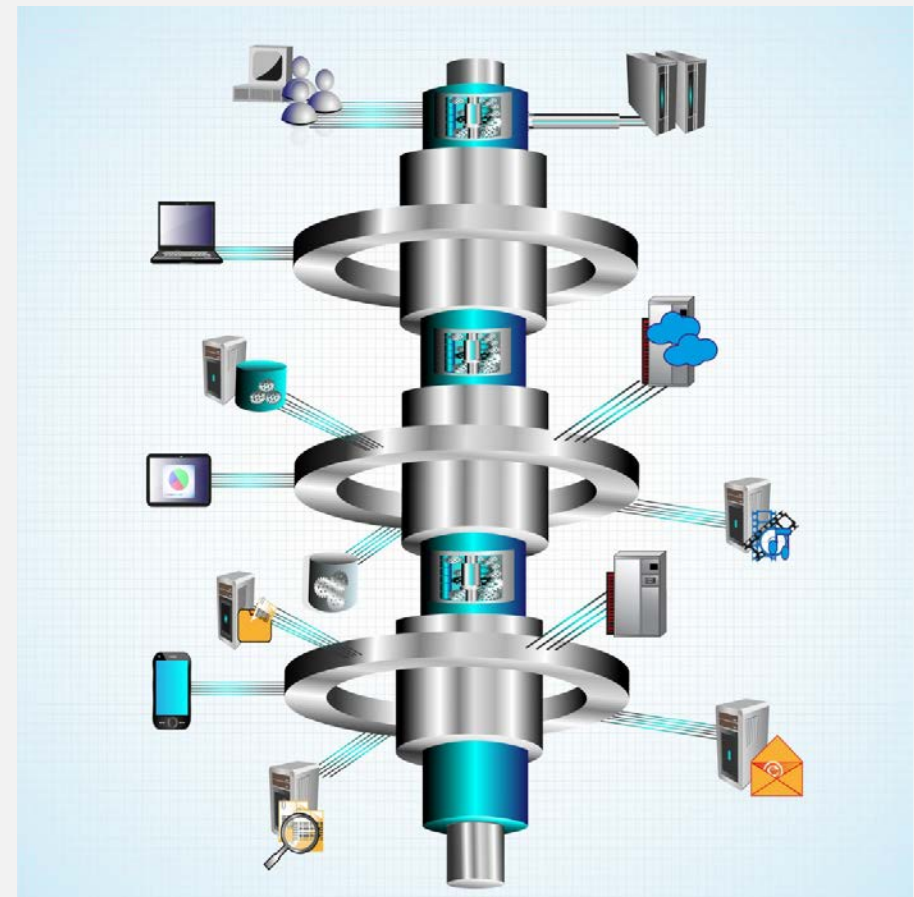
## Consider SaaS

Whether to adopt SaaS delivery is a fundamental consideration that must be a part of any current software selection. In particular, it may be a way to access validation-ready solutions. For more information on these considerations, please see *Choosing the Right PLM buyer's guide*. We believe it's wise to ensure that potential software vendors have a cloud strategy even if your company is not considering implementing the digital thread and PLM on the cloud. A software vendor that does not have a clear cloud strategy may be at business sustainability risk given the significant industry shift toward cloud computing.

SaaS has gained priority as remote work becomes more commonplace due to the impacts of COVID-19 where client/server and VPN-based technology stacks become impractical and greater levels of agility are essential.

## Consider Integration

Lastly, PLM does not hold all of the required data for the digital thread. Systems such as MES, ERP, Service Lifecycle Management, IoT, and others hold data that is highly valuable to the digital thread. It's vital to ensure that the solution you choose can easily integrate with other solutions to complete the digital thread.





# Vendor Considerations



## Support Today and Tomorrow

Any potential partner should be evaluated based on their ability to support your company today and their future business viability. Effective due diligence is no exception for PLM, and perhaps even more crucial given the long-term commitment most companies make to their PLM solution.

## Partner Knowledge

It's essential to ensure that your chosen vendor has a solid understanding of digital transformation as a whole in addition to understanding the digital thread. Look for business knowledge about digitalization in the life sciences industry in addition to technical knowledge about their solution. Digital transformation objectives across industries can differ widely. Given the breadth of the digital thread, it's also valuable to pick a provider with expertise spanning engineering, manufacturing, quality, IT, and service.

## Digital Capabilities

Evaluate the digital solutions available from your vendor. A platform or suite of solutions that includes both PLM and digital solutions such as IoMT and analytics can help ensure a smooth and effective transition. A comprehensive solution can make it easier to enrich the digital thread with performance data and expand digital thread value with analytics as Top Performers are more likely to do. Finally, your solution provider should have a strong ecosystem of partners and a willingness to partner to support the broad integration demands required to extend the digital thread beyond Engineering to the factory and the field.

# Conclusions and Next Steps

## Invest in the Digital Thread

Invest in the digital thread to streamline engineering and create digital continuity. Top Performers are 2.6 times as likely to view the digital thread as critical to supporting their business strategy.

## Extend the Thread across the Lifecycle

Adopt a comprehensive scope that incorporates cross-departmental data. Top Performers are more likely to include manufacturing, quality, and service plans in the scope of their digital thread, and enrich it with actual data from the IoT.

## Leverage PLM as the Digital Medical Device Backbone for Closed-Loop Quality, Continuity, and Streamlined Engineering

Adopt PLM to support the digital thread. Top Performing companies are 2.4 times as likely to view PLM as critical to supporting the digital thread and are much more likely to use PLM to support it.

## Enjoy the Benefits

The digital thread provides significant, measurable benefits including improved quality, increased engineering efficiency, enhanced innovation, faster time to market, and better compliance. Top Performers gain even higher benefits than others. For example, these more successful product developers enable their technical resources to spend 27% more time, on average, on value-added activities than their poorer performing counterparts.

Top Performing companies are 73% more likely to use PLM to support the digital thread.

# About the Research

## Data Gathering

Tech-Clarity gathered and analyzed over 250 responses to a web-based survey investigating the digital thread and PLM. Survey responses were gathered by direct e-mail, social media, and third party data collection.

## Industries

The respondents serve a variety of manufacturing industries. 21% are electronics / high tech, 20% consumer products, 19% industrial equipment / machinery, 16% automotive / transportation, 11% energy / utilities, 10% life sciences / medical devices, 10% building product / fabrication, and others.\*

Analysts further analyzed 26 respondents that do business in the medical device / life sciences industry to better understand their unique requirements.

## Company Size

The respondents represent a mix of company sizes, including 42% from smaller companies (less than \$250 million), 16% between \$250 million and \$1 billion, 21% between \$1 billion and \$5 billion, and 20% greater than \$5 billion. Company sizes were reported in US dollar equivalent.

## Geographies

Responding companies report doing business in North America (64%), Western Europe (47%), Asia (41%), Eastern Europe (17%), Australia (13%), Middle East (12%), Latin America (11%), and others including Africa.\*

## Role

The respondents are comprised of 27% manager level, 23% individual contributors / engineers, 18% executive

/ "C-level", 16% directors, 14% vice presidents, and 2% others.

## Organizational Function

Of the respondents, 31% serve in engineering / design roles, 18% in manufacturing, 17% in service / support, 14% in quality, 10% in IT, and others.

## Performance Banding

Top Performers represent the top 24% of responding companies in their ability to meet key product-related metrics across a variety of product development metrics (see right).

These companies were benchmarked to see what they do differently in regards to the digital thread and PLM in order to make recommendations to poorer performing companies.

**Top Performers represent the top 24% of responding companies in their ability to outperform their competitors in a variety of product-related metrics across the product lifecycle including:**

- **Designing innovative products**
- **Developing products quickly**
- **Developing products efficiently**
- **Meeting product cost targets**
- **Producing high quality products**
- **Providing excellent product service**

\* Note that the values total greater than 100% because companies reported doing business in multiple industries and geographies.

# Acknowledgments



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### About the Author

Jim Brown founded Tech-Clarity in 2002 and has over 30 years of experience in the manufacturing and software industries. Jim is an experienced researcher, author, and speaker and enjoys engaging with people with a passion to improve business performance through digital enterprise strategies and supporting software technology.

Jim is actively researching the impact of digital transformation and technology convergence in the manufacturing industries.

**Tech-Clarity** is an independent research firm dedicated to making the business value of technology clear. We analyze how companies improve innovation, product development, design, engineering, manufacturing, and service performance through the use of digital transformation, best practices, software technology, industrial automation, and IT services.



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### About this eBook

This is an update to our “Choosing Enterprise PLM to Support the Digital Thread” research originally published in 2020. This research includes additional data analysis to better understand the challenges, capabilities, and future plans medical device / life sciences companies have for PLM and the digital thread.

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